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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,284	03/01/2004	Kah Hiing Ling	USMO1825CNT 6	9509

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,284	LING ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *18-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A preliminary amendment was filed. Claims 1-17 are cancelled. Claims 18-32 are pending.

2. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "assayable amount" in claim 28 is used by the claim to be a quantitative limitation of the content of the active ingredients in the claim. Please note that the accepted meaning being a quantitative limitation must be a quantity which can be identified with an "assay method". The term is indefinite because the specification does not clearly redefine the term since no description nor enablement was found in the specification as to "what" assay procedure is the claim based upon. The quantity responsive in an assay procedure in a very sensitive procedure will be completely different from a screening procedure for which more error may be involved. In absence of *any* description of what the procedure may be, such term does not provide the meets and bounds of the scope. In so far as the quantities in a composition is the same as those useful in a therapeutic composition, the claim is a substantial duplicate of the pharmaceutical composition of claim 14 which is rejected as following.

3. Claims 18-32 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. Evidence that claims 18-32 fail to correspond in scope with that which applicants regard as the invention can be found in the reply filed Mar 1, 2004. In that paper, applicant has presented mere Markush variation **without** any structural formula for which the Markush elements are being drawn to. This statement indicates that the invention is different from what is defined in the claims 1-17 as originally filed and the scope can not be ascertained.

4. Claims 18-21, 27-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.
As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

Nature of invention

The field of antihistamine hydroxydiphenylmethylpiperidinyl compound art has been well recognized in the field to have unpredictable pharmacokinetics. The field has been well documented that the lead compounds such as terfenadine, instead of the basic compounds, the activity of the antihistamic effect was resulted from its first metabolite, i.e. the carboxylic acid derivative of the basic compound (see CA97:207743, CA 98:154). Please note that the instant claimed products are 1-methyl different compounds i.e. homolog of terfenadine. One methyl homologs are well recognized in the pharmaceutical art to have analogous activity. In re Wood 199 USPQ 137.

The state of the art and predictability

The field is highly complexed and unpredictable. For the lead compound terfenadine, the basic compound is known to have cardiotoxicity while the metabolite has antihistamic activity without the toxicity (see CA 123:187671).

The amount of guidance and working examples

Therefore, in absence of any factual data supporting such complexed process, the specification lacks sufficient enabling support for the claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-20 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by the small genus disclosed by Krauss et al. WO 95/00480 or US 6,147,216. Please note that with respect to the priority date of the instant application, the WO 95/00480 is a 102(a) reference and the US 6,147,216 is a 102(e) reference.

See '480, p.170, formula 72, supplemented by p. 3, W, R^1, R^2, A, m, n. US '216 col. 113-114 formula 72 supplemented by col. 1, W, R^1, R^2, A, m, n. Please note that the instant compound when R1 is CH_3 are drawn to formula 72 when the W is CH(OH), R1 and R2 are H, m is 0, n is 3, A is H or OH as disclosed by Krauss et al.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krauss et al. WO 95/00480 or US 6,147,216. Please note that with respect to the priority date of the instant application, the WO 95/00480 is a 102(a) reference and the US 6,147,216 is a 102(e) reference.

Determination of the scope and content of the prior art (MPEP §2141.01)

Krauss et al. WO or US patent disclosed the instantly claimed compounds with R1 being CH3 species well exemplified as pointed out supra in section 5 and hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The remaining variations of R1 being carboxylic acid or ester, CH2OH are also well delineated and exemplified in the whole reference with starting material and intermediates clearly identified and disclosed. Particularly, the preparation of intermediates on WO '480 pages 90 compound 38, p. 129, compound 55, p. 149 compound 66, or '216 col. 41 formula 22, 29, 35, col. 86, compound 55, 56, 57, col. 102 compound 66, clearly disclosed the variation of the broad Markush elements.

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the Krauss reference is clearly in possession of the instant claimed compounds **because** not only the variations have been generically disclosed by Krauss et al. but the modification and how to make the various starting material or intermediates have been clearly exemplified and guided by the reference to the making of the instant more limited scope of Krauss' compounds. In absence of unexpected result, there is nothing unobvious in choosing some among many. In re Lemin 141 USPQ 814.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 29, 2004-11-29

Celia Chang
Primary Examiner
Art Unit 1625